Randomized Trials
Discussion Points

- **Patients randomized to one of two or more trial arms may not be randomly distributed with respect to characteristics that affect their utilization, health status, etc.** Examples: significantly more patients with Medicaid or private insurance in one group versus another; more in HMOs vs. fee-for-service. These factors affect availability of home and community based services, pharmacy formularies, co-payments and deductibles. They may reflect differences in health status that are not observed.

- **Patients may not know critical information about some of these factors, however.** For example, what health plan they are in, what the benefits are, what co-payments or co-insurance rates apply.

- **With trials, we have to worry about sources of data about different systems (Medicare, VA, Medicaid).** For example, self-reports tend to be valid primarily for aggregates, not patient-level counts. Claims are available with a lag. Types of utilization are not necessarily the same (more later).

- **Unlike in observational studies, in trials patients often drop out before the study is finished.** Sometimes the researcher can get permission to check on a major outcome (e.g., death).

- **Risk adjustment may require reliable data on utilization and diagnoses prior to enrollment in the trial.** This issue may be addressed through self-reports.

- **Trials can combine survey or self-reports on factors that cannot be found in administrative data.** Examples: other measures of health status, informal caregiving, actual travel costs, time off from work, income.